

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

KANEKA CORPORATION,	)	
	)	
Plaintiff,	)	C.A. No. 21-209-RGA
	)	
v.	)	<b>JURY TRIAL DEMANDED</b>
	)	
DESIGNS FOR HEALTH, INC., and	)	
AMERICAN RIVER NUTRITION LLC,	)	
	)	
Defendants.	)	

**SECOND AMENDED ANSWER AND COUNTERCLAIM**

Defendants, Designs For Health, Inc. (“DFH”) and American River Nutrition, LLC (“ARN”) (collectively, “Defendants”), by counsel, hereby respond to the allegations in the Second Amended Complaint (“Complaint”) for Patent Infringement filed by Plaintiff, Kaneka Corporation (“Kaneka” or “Plaintiff”).

**NATURE OF THE ACTION**

1. Defendants admit only that Plaintiff purports to bring an action for patent infringement under federal law.

2. Defendants admit only that Plaintiff’s action purports to arise from DFH’s manufacture, use, offer for sale, and sale in the United States of the supplements DuoQuinol and CoQnol (“Accused Products”). Defendants admit that DuoQuinol is a form of Ubiquinol. Defendants further admit that Dr. Barrie Tan was a developer of DuoQuinol, and is the founder of ARN and Chief Science Officer of DFH. Defendants admit that DFH owns an interest in ARN. Defendants deny the remaining allegations in Paragraph 2 of the Complaint.

**THE PARTIES**

3. Defendants are without knowledge sufficient to admit or deny the allegations in Paragraph 3 and denies the same on this basis.

4. Defendants admit the allegations in Paragraph 4 of the Complaint.

5. Defendants admit the allegations in Paragraph 5 of the Complaint.

### **JURISDICTION AND VENUE**

6. Paragraph 6 of the Complaint contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the same.

7. Paragraph 7 of the Complaint contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the same.

8. Defendants admit the allegations in Paragraph 8 of the Complaint.

9. Defendants deny the allegations in Paragraph 9 of the Complaint.

10. Paragraph 10 of the Complaint contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the same.

### **BACKGROUND**

11. Defendants are without knowledge sufficient to admit or deny the allegations in Paragraph 11 and denies the same on this basis.

12. Defendants admit that the Accused Products are a form of Ubiquinol. Defendants deny that Plaintiff is the only company that has the legal right to produce and sell Ubiquinol in the United States. Defendants are without knowledge sufficient to admit or deny the remaining allegations in Paragraph 12 and denies the same on this basis.

13. Defendants are without knowledge sufficient to admit or deny the allegations in Paragraph 13 and denies the same on this basis.

14. Defendants are without knowledge sufficient to admit or deny the allegations in Paragraph 14 and denies the same on this basis.

### **THE ASSERTED PATENTS**

15. Defendants admit that a purported copy of United States Patent No. 7,145,044 (“the ‘044 Patent”) is attached as Exhibit A to the Complaint. Defendants state that the ‘044 Patent, together with its prosecution history, speaks for itself and denies the remaining allegations in Paragraph 15.

16. Defendants admit that a purported copy of United States Patent No. 7,829,080 (“the ‘080 Patent”) is attached as Exhibit B to the Complaint. Defendants state that the ‘080 Patent, together with its prosecution history, speaks for itself and denies the remaining allegations in Paragraph 16.

### **THE DFH INFRINGING PRODUCTS AND ACTIVITIES**

17. Defendants admit that the Accused Products purport to be DuoQuinol and CoQnol, and that DuoQuinol is a form of Ubiquinol, which could be derived from Ubiquinone through a process involving the use of geranygeraniol (GG) and ascorbyl palmitate. They further admit that Dr. Barrie Tan was a developer of DuoQuinol. Defendants deny that CoQnol includes DuoQuinol plus GeranyGeraniol (GG) and ascorbyl palmitate, as alleged by Plaintiff. Defendants are without knowledge sufficient to admit or deny the remaining allegations in Paragraph 17 and denies the same on this basis.

18. Defendants admit only that the videos identified in Paragraph 18 and in Paragraph 19 were published online and are accessible at the links provided. Defendants deny that the statements made in the videos are attributable to Defendants. Defendants deny the remaining allegations in Paragraph 18 of the Complaint.

19. Defendants admit only that the videos identified in Paragraph 18 and in Paragraph 19 were published online and are accessible at the links provided. Defendants deny that the

statements made in the videos are attributable to Defendants. Defendants deny the remaining allegations in Paragraph 19 of the Complaint.

20. Defendants state that the video linked in Paragraph 18 speaks for itself. Defendants deny that the statements made in the video are attributable to Defendants. Defendants deny the allegations in Paragraph 20 of the Complaint to the extent they assume the accuracy of any statements made in the video or deviate from or mischaracterize the contents of the video.

21. Defendants state that the video linked in Paragraph 18 speaks for itself. Defendants deny that the statements made in the video are attributable to Defendants. Defendants deny the allegations in Paragraph 21 of the Complaint to the extent they assume the accuracy of any statements made in the video or deviate from or mischaracterize the contents of the video.

22. Defendants state that the video linked in Paragraph 19 speaks for itself. Defendants deny that the statements made in the video are attributable to Defendants. Defendants deny the allegations in Paragraph 22 of the Complaint to the extent they assume the accuracy of any statements made in the video or deviate from or mischaracterize the contents of the video.

23. Defendants deny the allegations in Paragraph 23 of the Complaint.

24. Defendants deny the allegations in Paragraph 24 of the Complaint.

25. Defendants deny the allegations in Paragraph 25 of the Complaint.

26. Defendants deny the allegations in Paragraph 26 of the Complaint.

**COUNT I**  
**(Direct Infringement of the '044 Patent by DFH)**

27. Defendants incorporate the responses to each of the preceding paragraphs as if fully set forth herein.

28. Defendants deny the allegations in Paragraph 28 of the Complaint.

29. Defendants admit that Plaintiff purports to quote claim 13 of the '044 Patent and state that the '044 patent, together with its prosecution history, speaks for itself, and denies the remaining claims of Paragraph 29 of the Complaint.

30. Defendants deny that DFH infringes a valid claim 13 of the '044 patent and are without knowledge sufficient to admit or deny the remaining allegations in Paragraph 30 and denies the same on this basis.

31. Defendants deny the allegations in Paragraph 31 of the Complaint. Defendants specifically deny the allegations in Paragraph 31 on the basis that Exhibit E is not attached to the Complaint.

32. Defendants deny the allegations in Paragraph 32 of the Complaint.

33. Defendants deny the allegations in Paragraph 33 of the Complaint.

**COUNT II**  
**(Direct Infringement of the '080 Patent by DFH)**

34. Defendants incorporate the responses to each of the preceding paragraphs as if fully set forth herein.

35. Defendants deny the allegations in Paragraph 35 of the Complaint.

36. Defendants admit that Plaintiff purports to quote claim 5 of the '080 Patent and state that the '044 patent, together with its prosecution history, speaks for itself, and denies the remaining claims of Paragraph 36 of the Complaint

37. Defendants deny that DFH infringes a valid claims 1, 5 or 15 of the '080 patent and are without knowledge sufficient to admit or deny the remaining allegations in Paragraph 37 and denies the same on this basis.

38. Defendants deny the allegations in Paragraph 38 of the Complaint. Defendants specifically deny the allegations in Paragraph 38 on the basis that Exhibit E is not attached to the Complaint.

39. Defendants deny the allegations in Paragraph 39 of the Complaint.

40. Defendants deny the allegations in Paragraph 40 of the Complaint.

**COUNT III**  
**(Induced Infringement by ARN of the '044 and '080 Patents)**

41. Defendants incorporate the responses to each of the preceding paragraphs as if fully set forth herein.

42. Defendants deny the allegations in Paragraph 42 of the Complaint.

43. Paragraph 38 cites and discusses a U.S. Supreme Court case and calls for a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations in paragraph 43.

44. Defendants deny the allegations in Paragraph 44 of the Complaint.

45. Defendants deny the allegations in Paragraph 45 of the Complaint.

To the extent not set forth above, Defendants deny each and every allegation of the Complaint that is not specifically and expressly admitted herein.

**DEFENSES**

1. Plaintiff's claims are barred, in whole or in part, because they fail to state claims upon which relief can be granted.

2. Plaintiff does not have standing to sue one or both Defendants and subject matter jurisdiction does not exist.

3. Plaintiff's claims are barred, in whole or in part, because of estoppel and other equitable relief, including, without limitation, prosecution laches, prosecution history estoppel,

and prosecution disclaimer, and because Plaintiff based its applicable inconsistent positions taken during patent prosecution and in legal proceedings adverse to one or more persons.

4. Plaintiff's claims are barred, in whole or in part, because of waiver on the basis of Plaintiff's prior conduct and lack of action inconsistent with the claims asserted in the Complaint.

5. Plaintiff's claims are barred, in whole or in part, because its asserted patent rights are invalid under the application of Title 35 of the United States Code to the patent rights Plaintiff seeks to assert in support of its claims, including under one or more provisions of 35 U.S.C. §§ 101, 102, 103, or 112, or based on other judicially-recognized bases for invalidation.

6. Plaintiff's claims are barred, in whole or in part, because its asserted patent rights are unenforceable under the application of Title 35 of the United States Code to the patent rights Plaintiff seeks to assert in support of its claims.

7. Plaintiff's claims are barred because Defendants do not infringe any valid claim of the patents-in-suit.

8. Plaintiff's claims are barred, in whole or in part, under the first sale doctrine. On information and belief, Defendants purchased CoQ10 from Kaneka. At least some of the CoQ10 utilized in the Accused Products was purchased from Kaneka. On information and belief, CoQ10 purchased from Kaneka was present in substantially the same form as that which is defined by any asserted claims of the '044 Patent and the '080 Patent and incorporated into the products, made, used, and/or sold by Defendants.

9. Plaintiff's claims are barred, in whole or in part, because of its failure to mitigate its alleged damages.

10. Plaintiff is not entitled to injunctive relief, having not suffered any irreparable injury, or to any specific performance; it has an adequate remedy available at law for any alleged wrongdoing.

11. Defendants respectfully reserve the right to assert any and all additional defenses as may be determined to be applicable during the course of discovery.

### **COUNTERCLAIM**

Counterclaim-Plaintiffs, Designs For Health, Inc. (“DFH”) and American River Nutrition, LLC (“ARN”) (collectively, “Counterclaim-Plaintiffs”), by counsel, allege the following counterclaims against Kaneka Corporation (“Kaneka” or “Counterclaim Defendant”).

### **Parties**

1. Counterclaim-Plaintiff DFH is a Delaware corporation located at 14 Commerce Blvd., Palm Coast, Florida 32164.

2. Counterclaim-Plaintiff ARN is a Delaware limited liability company located at 333 Venture Way, Hadley, Massachusetts 01035.

3. Counterclaim Defendant has represented to this Court that it is a Japanese Corporation with a head office at 1-12-32, Akasaka, Minato-Ku, Tokyo, Japan, and a head office at 2-3-18, Nakanoshima, Kita-Ku, Osaka, Japan.

### **Jurisdiction and Venue**

4. This Counterclaim arises under Title 35 of the United States Code. The Court has subject matter jurisdiction over this Counterclaim pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

5. This Court has personal jurisdiction over Counterclaim Plaintiff because, *inter alia*, in filing the Complaint, it has submitted itself to the jurisdiction of the Court.



6. Venue is satisfied in this matter because, *inter alia*, Counterclaim Plaintiff has sought the benefit of this forum for this litigation.

7. A justifiable controversy exists between DFH, ARN, and Counterclaim- Defendant with respect to the invalidity and non-infringement of the claims of United States Patent No. 7,145,044 (“the ‘044 Patent”) and by virtue of the allegations contained in Counterclaim-Plaintiff’s Complaint and Counterclaim Plaintiffs’ Answer.

8. A justifiable controversy exists between DFH, ARN, and Counterclaim- Defendant with respect to the invalidity and non-infringement of the claims of United States Patent No. 7,829,080 (“the ‘080 Patent”) and by virtue of the allegations contained in Counterclaim-Plaintiff’s Complaint and Counterclaim Plaintiffs’ Answer.

**First Count**  
**(Declaration of Non-Infringement of the ‘044 Patent)**

9. Counterclaim-Plaintiffs incorporate herein by reference the allegations of its Answer and the foregoing Counterclaim allegations as if fully set forth herein.

10. Counterclaim-Plaintiffs are not infringing and have not infringed or induced the infringement of any valid claim of the ‘044 patent, whether literally or by equivalents.

11. Counterclaim-Plaintiffs are entitled to a declaration pursuant to 28 U.S.C. § 2201 that neither it nor its products infringes or has infringed, whether directly or indirectly, literally or by equivalents any claim of the ‘044 patent.

**Second Count**  
**(Declaration of Non-Infringement of the ‘080 Patent)**

12. Counterclaim-Plaintiffs incorporate herein by reference the allegations of its Answer and the foregoing Counterclaim allegations as if fully set forth herein.

13. Counterclaim-Plaintiffs are not infringing and have not infringed or induced the infringement of any valid claim of the '080 patent, whether literally or by equivalents.

14. Counterclaim-Plaintiffs incorporates herein by reference the allegations of its Answer and the foregoing Counterclaim allegations as if fully set forth herein.

15. Counterclaim-Plaintiffs are entitled to a declaration pursuant to 28 U.S.C. § 2201 that neither it nor its products infringes or has infringed, whether directly or indirectly, literally or by equivalents any claim of the '080 patent.

**Third Count**  
**(Declaration of Invalidity of the '044 Patent)**

16. Counterclaim-Plaintiffs incorporates herein by reference the allegations of its Answer and the foregoing Counterclaim allegations as if fully set forth herein.

17. Each claim of the '044 patent is invalid for failure to comply with the conditions and requirements for patentability under the patent laws of the United States, Title 35 U.S.C. § 101 *et seq.*, including without limitation, §§ 101, 102, 103 or 112.

18. Counterclaim Plaintiffs are entitled to a declaration pursuant to 28 U.S.C. § 2201 that each of the claims of the '044 patent is invalid.

**Fourth Count**  
**(Declaration of Invalidity of the '080 Patent)**

19. Counterclaim-Plaintiffs incorporate herein by reference the allegations of its Answer and the foregoing Counterclaim allegations as if fully set forth herein.

20. Each claim of the '080 patent is invalid for failure to comply with the conditions and requirements for patentability under the patent laws of the United States, Title 35 U.S.C. § 101 *et seq.*, including without limitation, §§ 101, 102, 103 and/or 112.

21. Counterclaim Plaintiffs are entitled to a declaration pursuant to 28 U.S.C. § 2201 that each of the claims of the '080 patent is invalid.

**PRAYER FOR RELIEF**

WHEREFORE, Defendants respectfully pray for judgment as follows:

1. That the Court enter judgment in favor of Defendants and against Plaintiff on all claims and counterclaims for relief;
2. That the Court deny any preliminary or permanent injunction sought by Plaintiff;
3. That the Court issue a declaratory judgment that the claims of the patents-in-suit are neither infringed nor valid;
4. That the Court deny Plaintiff's demand for damages and attorneys' fees;
5. That all costs be assessed against Plaintiff;
6. That, if Defendants are the prevailing party, the Court find this case to be exceptional and award them their attorneys' fees under 35 U.S.C. § 285; and
7. That the Court award such other and further relief to Defendants as shall appear just and proper.

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